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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/060,188 04/14/98 BEHAN

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HM12/0510

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EXAMINER

BASI, N

ART UNIT

PAPER NUMBER

1646

*15*

DATE MAILED:

05/10/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/060,188**

Applicant(s)  
**BEHAN et al**

Examiner  
**Nirmal. S. Basi**

Group Art Unit  
**1646**



☒ Responsive to communication(s) filed on Feb 16, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-18, 33, 34, 39, and 40 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-18, 33, 34, 39, and 40 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-18, 33, 34, 39, and 40 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on Feb 16, 2000 is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

1. Amendments filed 2/16/00 has been entered.

***Drawings***

2. Figure 12 is objected to because drawings are of not of sufficient quality to permit  
5 examination. Accordingly, new drawings are required in reply to this office action.

***Response to Amendment***

3. The rejections under 35 U.S.C. 112, second paragraph, in paper number 12, 1/20/00 are  
withdrawn in light of applicants' amendments and arguments filed on 2/16/00.

***Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph***

10 The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or  
composition of matter, or any new and useful improvement thereof, may obtain a patent  
therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

15 The specification shall contain a written description of the invention, and of the manner and  
process of making and using it, in such full, clear, concise, and exact terms as to enable any  
person skilled in the art to which it pertains, or with which it is most nearly connected, to  
make and use the same and shall set forth the best mode contemplated by the inventor of  
20 carrying out his invention.

4. Claims 1-18, 33-34 and 39-40 are rejected under 35 U.S.C. 101 because the claimed  
invention is not supported by either a specific and substantial asserted utility or a well established  
utility.

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A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention.

Applicant has asserted utilities for the specifically claimed invention of claims 1-18, 33-34 and 39-40. For example, the specification at page 31 asserts, "The fundamental insight underlying the present invention is the recognition that it is the constitutively activated form of receptors which can be used to directly identify lead compounds which affect receptor activity", and further states that, "Essentially, the method of this invention provides a means for discovering modulators of receptor function without the need for any knowledge of the endogenous ligand".

The utilities asserted by Applicant are specific. However, the asserted utilities are not substantial. Because an orphan receptor, does not have, by definition, a corresponding endogenous ligand that is known, the specification nor the art of record disclose the function of orphan receptors, the proteins they modulate and their effects on specific disease states. Similarly, constitutively activated orphan receptors have no known function. Thus the corresponding

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asserted utilities are essentially methods of identify lead compounds which affect constitutively activated orphan receptor activity, which does not define a "real world" context of use. Therefore identifying compounds that interact with orphan receptors would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed method of identifying compounds having activity of inverse agonist or agonist activity, further experimentation is necessary to attribute a utility to constitutively activated orphan receptors and to the compounds that bind the constitutively activated orphan receptors. See *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

5. Claims 1-18, 33-34 and 39-40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

No claim is allowed.

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**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
Art Unit 1646  
May 1, 2000

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER